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Development of a near-infrared spectroscopy interface able to assess oxygen recovery kinetics in the right and left sides of the pelvic floor

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Abstract. Near-infrared spectroscopy (NIRS) muscle oxygenation data are relied on in sports medicine. Many women with urinary incontinence (UI) have dysfunctional pelvic floor muscles (PFMs) but their evaluation lacks such measures; a transvaginal NIRS interface would enable the PFM to be interrogated. Paired miniature fiber-optic cables were configured on a rigid foam insert so their emitter detector arrays with an interoptode distance of 20 mm apposed the right and left inner sides of a disposable clear plastic vaginal speculum, and linked to a standard commercial NIRS instrument. Measurement capability was assessed through conduct of three maximum voluntary contractions (MVCs) and one sustained maximum voluntary contraction of the PFM with calculation of HbDiff (½RT), a validated muscle reoxygenation kinetic parameter. In all four asymptomatic controls, mean age 40, mean BMI 21.4, MVCs were associated with changes in PFM oxyhemoglobin (O_2Hb), deoxyhemoglobin (HHb) concentration, and their difference (HbDiff) comparable to those in voluntary muscle sports medicine studies. NIRS data during recovery (reoxygenation) allowed calculation of HbDiff (½RT). New techniques are called for to evaluate UI. This NIRS interface warrants further development as the provision of quantitative reoxygenation kinetics offers more comprehensive evaluation of patients with PFM dysfunction.
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Keywords: oxygen kinetics; near-infrared spectroscopy; pelvic floor muscle; photonics; urinary incontinence.

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1 Introduction

New techniques to improve health care for women with urinary incontinence (UI) are called for.[1] Novel optical systems have been applied in urology, including direct measurement of bladder muscle oxygenation and hemodynamics using near-infrared spectroscopy (NIRS).[2] But, for assessment of pelvic floor muscle (PFM) function, which is central to treatment for UI using pelvic floor muscle therapy (PFMT),[3] measurement parameters relating to oxygen recovery kinetics are lacking, yet, in sports medicine such parameters are currently measured using NIRS.[4–6]

The pelvic floor comprises a layer of muscles that span the floor of the pelvis, and provides a voluntarily control mechanism for maintaining urinary continence. Urinary incontinence, defined as involuntary loss of urine,[1] affects the quality of life of 15.7% of U.S. women.[7] A wide variety of pathologies lead to UI by causing dysfunction of the PFM, including trauma induced by vaginal birth delivery, neuromuscular compromise due to congenital anomalies or spinal cord injury, and neurologic diseases such as multiple sclerosis and Parkinson's.[8–10] Importantly, while the entire PFM complex may be involved, dysfunction can also be lateralized to one side or the other; the resulting compromise of muscle strength and differences between the right and left sides cannot be adequately assessed by current clinical measures.

Our objective was to develop an interface for NIRS-based measurement of oxygen kinetic parameters as a potential aid to improving the management of women with UI through more comprehensive physiologic evaluation. Importantly, in the context of applying NIRS, the tissues of the vaginal wall overlying the PFM consist of three layers, the mucosa, the muscularis, and the adventitia, but, unlike many locations where NIRS is used, there is no fat layer within the optical field. The emitter detector array is apposed against the vaginal mucosa and the tissues between it, and the superficial and deep muscle layers of the PFM are composed of nonkeratinized stratified squamous epithelium and supporting connective tissue.

Key specifications required included a probe suitable for housing the interface for transvaginal measurement and the capability to simultaneously measure chromophore changes in the right and left sides of the PFM during conduct of the exercise regimen used in PFMT for UI. Following development, the capability of the new interface was tested in volunteer control subjects.

2 Materials and Methods

2.1 *Dual-Channel Bidirectional Interface for PFM NIRS Measurement*

The NIRS instrument linked to the interface was an "Oxymon" MK III (Artinis Medical Systems BV, The Netherlands). The principles of NIRS have been comprehensively described,[5,11–14] and the specifications of this CW NIRS device and details of modified Beer–Lambert law employed have been published previously.[11,14]

The interface components were configured so they could be incorporated within a clear plastic single use vaginal speculum ("Pederson," The Stevens Company, Canada). A dual-channel array was created by placing two paired fiber-optic cables

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parallel to each other so that an emitter and detector optode would be in contact with the right and left walls of the speculum. Due to size constraints within the speculum, customized miniature fiber-optic cables were used; these had a 1-mm internal fiber bundle and incorporated 90-deg optodes at the tip, measuring 3-mm wide, 8-mm long, and 4-mm deep. The miniature cables were connected to the standard cables of the Oxymon (transmitter bundle 4 mm and receiver bundle 3.3 mm) via an adapter block. The block is completely opaque to prevent any external light contamination at the attachment point. During data collection, the block with the joined cables was also covered with a black cloth to further protect against environmental light contamination.

The fiber-optic cables and terminal optodes were secured to a dense foam inlay, which was shaped so that its location was held constant within the speculum to ensure consistent optode position and prevent any change in interoptode distance (IOD) across all measurements. Placement of the foam inlay positioned the optodes 2 cm from the end of the speculum housing. This point was chosen so that, on transvaginal insertion up to a defined mark, the optodes would be emitting/detecting light into/from the PFM. The IOD for each emitter/detector was set at 20 mm to achieve a tissue penetration depth of ~10 mm into the PFM microvasculature. The interface, comprised of the foam insert with attached NIRS cables and optodes, was designed to be removable so that it could be reused within a single use speculum for each subject's measurement. For reasons of hygiene, as the speculum was not sealed, it was covered with a latex-free condom prior to insertion; in a prior unpublished evaluation of multiple products, the one chosen was confirmed not to adversely impair NIR photon transmission nor result in problematic light channeling.

Four wavelengths of NIR light were transmitted to the emitter detector arrays in the interface from the Oxymon—766, 861, 906, and 971 nm. Raw optical data were captured at 10 Hz; from these, concentration changes in oxyhemoglobin (O_2Hb) and deoxyhemoglobin (HHb) were derived, and the difference between the two (HbDiff) was calculated for the right and left pelvic floor musculature using proprietary software ("Oxysoft," Artinis, BV, The Netherlands).[11] A fixed differential path length factor (DPF) of 4 was used, based on prior studies employing the same NIRS equipment investigating skeletal muscle tissue.[12,15] Gain settings were adjusted at the beginning of each measurement to prevent oversaturation and maintain acceptable signal strength within the range of 1% to 20%.[11]

In Fig. 1, the final iteration of the interface is shown housed inside the disposable speculum used for transvaginal measurement. The configuration of the emitter and detector arrays and their location 2 cm from the tip of the housing are shown; these allow simultaneous measurements from the right and left sides of the PFM. The dual-channel design consists of one emitter and one detector at the end of miniature fiber-optic cables secured to a foam inlay so as to maintain a constant IOD of 20 mm, and appose the paired right and left sided optodes parallel to each other, and against the translucent wall of the speculum housing the interface.

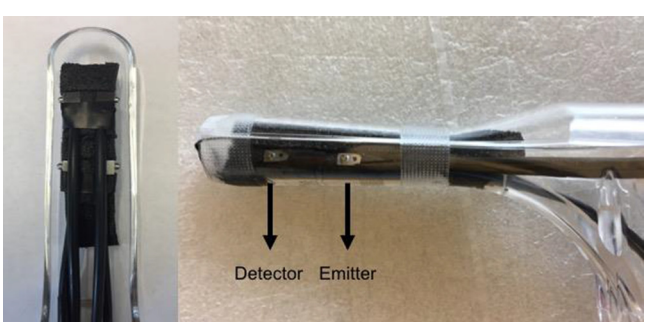

Fig. 1 Prototype NIRS interface and speculum housing.

3 Clinical Protocol for Pilot Evaluation/ Validation

We experimentally tested the dual-channel bidirectional interface using a clinical protocol approved by the University of British Columbia's Research Ethics Board. Subjects were healthy community dwelling volunteer women who provided written informed consent prior to participation in this prospective cohort study. Subjects across a wide age range were recruited because the population of women with UI due to PFM dysfunction includes both pre and postmenopausal women and also as age and menopausal status likely generate physical changes of potential relevance to conduct of future NIRS muscle studies to quantify PFM oxygen kinetics. A registered nurse taught participants how to perform PFM contractions used in PFMT; correct conduct was confirmed by visual inspection of perineal elevation.[16,17]

The exercise sequence used was a standardized series of three maximum voluntary contractions (MVCs) followed by a 5-min recovery period and then one sustained maximum voluntary contraction (SMVC).[3,17] Subjects were positioned supine, in the "butterfly" position,[18] and the speculum housing the NIRS interface introduced into the vagina up to a defined mark with the handle positioned in the midline; this ensured a consistent depth of insertion and apposition of the emitter detector arrays against the right and left sides of the vaginal wall in immediate proximity to the underlying PFM.

Speculum insertion is illustrated in the diagram in Fig. 2.

The Oxymon was then turned on, the output adjusted to achieve acceptable signal percentages, and the data stream biased to an arbitrary zero. Resting chromophore concentration values were then recorded prior to initiating the PFM contraction sequence.

4 NIRS Data Analysis and Outcome Measures

Prior to analysis, the Oxysoft software was used to apply a moving average Gaussian filter which uses filters at a width of 1 s and calculates the average within that 1 s time point; use of this and similar filters is reported in the NIRS literature.[15,19,23] The data were also set to of an arbitrary value zero with 30 s prior to the onset of each contraction averaged as baseline.

4.1 *NIRS Chromophore Parameters*

Four NIRS variables were derived from each contraction set (O_2Hb, HHb, tHb, and HbDiff). However, HbDiff was selected for analysis, as this parameter represents relative oxygen saturation in occlusion-free oxygen recovery analysis, is considered to be more indicative of metabolic changes within the muscle tissue, and less susceptible to blood flow changes than O_2Hb.[15,19,21,22] Also, the responsiveness of HbDiff during exercise is a measure of coupled oxygen demand and supply, and during recovery from exercise it provides an index of oxygen delivery.[23] Similarly, for analysis of the oxygen kinetic measure chosen, HbDiff (½RT), we used SMVC data, because SMVC

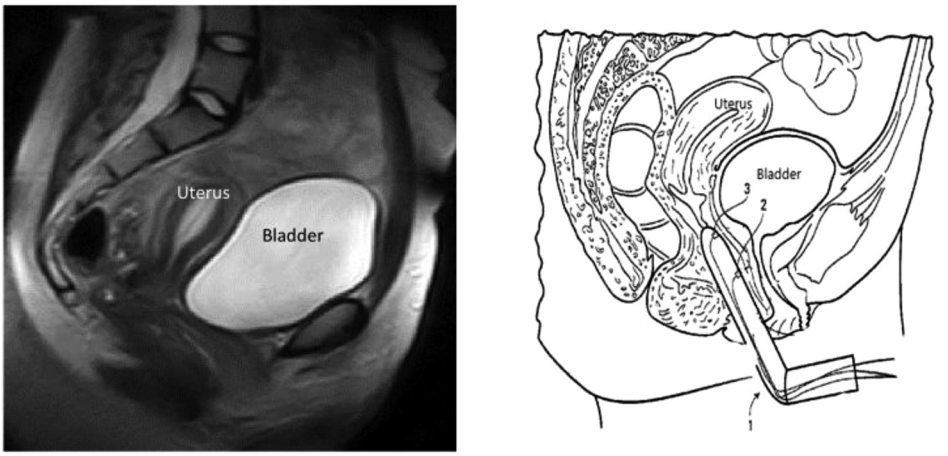

Fig. 2 A composite image showing a magnetic resonance image of the pelvis taken in the standing position (a) and a schematic showing a cross section through the pelvis, pelvic organs and pelvic floor muscle with the speculum housing the interface inserted (b). Legend: 1 = Speculum containing NIRS interface in the vagina; 2 and 3 = NIRS interface emitter/detector array.

requires more continued force production than MVC, so these contractions better reflect the effects of O_2 demand[20] and hence are a good measure of both strength and endurance.[3,24]

4.2 *Half-Recovery Time of HbDiff (½RT)*

Calculations of this oxygen kinetic parameter are based on the slope of the recovery from the point where muscular work (SMVC) ends to the point of maximum resaturation.[24] We used a recovery time interval of 90 s after contraction cessation for our ½RT calculations, based on adaption of the original method by McCully et al.[23] and subsequent studies employing this methodology for HbDiff ½RT analysis.[20,25]

5 Results

Four asymptomatic volunteers were studied; the demographic data are summarized in Table 1.

Table 1 Participant demographics.

	Participant				
	1	2	3	4	Mean (±1 SD)
Age (years)	30	34	62	33	40 (15)
BMI (kg/m^2)	20.7	20.2	22.1	22.5	21.38 (1.10)
Parity	0	2	2	0	1 (1.15)
Menopause	0	0	1	0	0.25 (0.50)
Life style index	2	1	2	2	1.75 (0.50)

Note: Life style index (scored as: 0 = "sedentary" no physical exercise, 1 = "moderately active" 20 min of vigorous intensity physical activity 3 days/week, and 2 = "active" 30 min of moderate intensity physical activity 5 days/week). Menopause (scored as: 0 = premenopausal and 1 = menopausal).

5.1 *HbDiff SMVC Response*

In Fig. 3, the patterns of desaturation seen in the four controls on the right and left side during each SMVC are illustrated. A decline in HbDiff is evident from the onset of the sustained contraction, with resaturation occurring in recovery following cessation of contraction; these patterns of chromophore change are consistent with NIRS-derived skeletal muscle oxygenation patterns described in the literature in response to exercise.[5,23,26]

5.2 *Half-Recovery Time of HbDiff (½RT)*

The points used to define the interval from which HbDiff (½RT) are calculated are described in Fig. 3. Table 2 shows the right and left side values calculated for muscle reoxygenation using HbDiff (½RT). In all four subjects, differences are evident between the two sides of their PFM; such differences are attributed to the natural dominance of one side of the body over the other in prior studies of muscle strength and function.

6 Discussion

We describe an application of an established optical technique with the potential to improve health care for women with UI due to PFM dysfunction. A speculum-housed interface incorporating a dual-channel NIRS emitter/detector array was developed iteratively and linked via fiberoptic cables to a commercial four wavelength CW NIRS instrument. The feasibility of monitoring oxygen kinetics in the right and left sides of the pelvic floor transvaginally during a standardized protocol of MVC was confirmed in four control subjects.

Qualitative checks confirmed that the system allowed capture of NIRS data of good quality with minimal noise from the muscles of the pelvic floor. We then evaluated the device clinically and identified that the patterns of chromophore change obtained matched those seen in NIRS studies involving MVC of other voluntary muscles.

The goal of showing the feasibility of obtaining oxygen kinetic data of relevance from the PFM was achieved. The decline of HbDiff during contraction reflects oxidative metabolism of the musculature.[20] The return to resting levels on

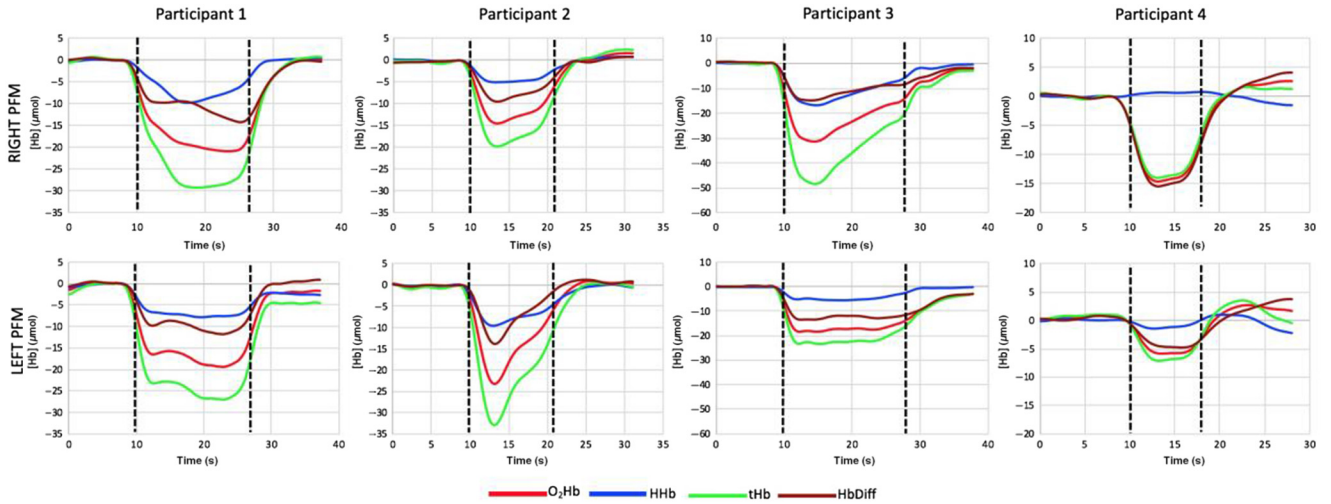

Fig. 3 Simultaneous bilateral PFM Hb response during SMVC of four participants. Vertical dotted lines indicated SMVC onset and cessation. Inclusive of 10 s prior to SMVC onset and 10 s following SMVC cessation. The interval used to calculate HDiff (½RT) extends from the point at which SMVC ends to the point of maximal reoxygenation.

Table 2 Comparison of right and left PFM ½RT HbDiff measurements.

	Participant				
	1	2	3	4	Mean (±SD)
Right PFM ½RT (s)	3.9	2.5	4.1	3.2	3.43 (0.73)
Left PFM ½RT (s)	2.0	1.7	6.8	5.0	3.88 (2.45)

cessation of contraction allows muscle reoxygenation to be quantified via calculation of half-recovery time of HbDiff, as there is a direct and proportional relationship between blood flow and O_2 consumption. The more rapidly HbDiff returns to resting level (shorter ½RT), the better the PFM is meeting the metabolic demand of contraction.[15,20,27]

Improved techniques are called for in the evaluation of UI in women, as there is no standardized methodology for quantifying the measures of strength and endurance currently relied on in PFM assessment.[1,3,28,29] This is problematic in planning clinical treatment employing PFMT, and in those with impaired pelvic innervation, no effective evaluation may be possible as they commonly only manage very weak contractions that can be indiscernible by an examiner or go undetected by current pressure monitoring devices. In sports medicine, however, measurements of oxygen kinetics are routinely performed to optimize athletic training regimens. NIRS can provide *in vivo* assessment of the workload capacity of muscle (oxygen extraction) and fatigue resistance (oxygen recovery) during exercise and makes sensitive and specific detection of localized skeletal muscle oxygenation patterns of targeted tissue possible.[5,13,26] NIRS has been validated against gold standard measures of muscle biopsy and ^{31}P-MRS[30] and is also an established research modality for evaluating oxygen kinetics in states of health and disease.[4–6,13]

Our team proved the feasibility of transvaginal monitoring of NIRS-derived changes in chromophore concentration with a prior probe prototype designed to interrogate the bladder detrusor muscle and internal sphincter during voiding. Previous attempts to develop intravaginal NIRS probes have been few in number, and limited to attempts to monitor cerebral oxygenation during passage of the fetus through the birth canal.[31] These applications were limited by difficulties sustaining apposition against the fetal head, and intrapartum monitoring remained compromised by movement artifacts. Our first probe was limited by only being able to measure in one plane as it was configured with one emitter and two detector optodes, and required repositioning to monitor each targeted site, was prone to movement during measurement, and early iterations suffered from compromised photon transmission.[31] In contrast, the interface we now describe overcomes these deficiencies and offers an innovative approach as it provides a means of quantifying changes in oxygenation in the right and left sides of the PFMs. Bilateral measurement is of obvious relevance in patients with unilateral neurologic impairment but also, in health, a subject's muscle function commonly differs between the left and right sides of the body. With further development, this NIRS interface has the potential to improve the understanding of female UI by responding to the call for new techniques to improve health care for women with UI,[1] and adding the ability to quantify oxygen kinetics to the evaluation and management of the large number of women with UI due to PFM dysfunction.[7]

We recognize limitations in what we report. The transparent plastic of the speculum housing the NIRS components will impact photon transmission, likely causing some scatter and refraction; however, data of good quality were obtained and the high-density, opaque foam insert represents an improvement over our initial single-channel probe design where photons were refracted by the wall of speculum in which it was housed. We did determine previously that movement artifacts do not compromise the NIRS data, provided the position of the speculum is maintained by the operator via the incorporated handle during measurement. The pathlength factor specific to the PFM has not been identified; based on previous CW NIRS studies of skeletal muscle, a fixed DPF value of 4 was used.[12,15] Pathlength will also be variable from one subject to the next;[32] however, the principal value of this NIRS system is the ability to evaluate an individual patient rather than make intersubject comparisons. However, an advantage of using HbDiff (½RT) as a metric to

assess the PFM is that it is independent of DPF. Our sample is limited; no statistical measures were feasible, however, the PFM contraction sequence used followed a recommended assessment protocol. And, our functional analysis reported SMVC data as these contractions reflect the effects of O_2 demand better than MVC because they require more continued force production and are considered a good measure of both strength and endurance. Individuals naturally vary in how long they can sustain an MVC because force and endurance naturally differ due to variations in muscle function; some PFM retraining regimens employ fixed intervals, but holding contractions over time and achieving stronger and longer contractions are core components of PFM retraining[3,17] Differences were evident between HbDiff (½RT) values for subject's right and left sides; while this is more likely reflects variation due to the natural dominance of one side of the body over the other than a technical effect, this will be clarified by further studies.

We suggest that, with the interface described, this NIRS system is suitable for further trials and exploration of its potential to more comprehensively evaluate patients with pelvic floor dysfunction through the provision of quantitative oxygen kinetics that are currently not available by other means.

Disclosures

The authors have no conflicts of interest to declare.

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